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K 002062

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
November 1, 2000

Submitter's Information: 21 CFR 807.92(a)(1)
SAMSUNG SDS CO., LTD
707-19, Yoksam-Dong, Kangnam-Gu,
Seoul, Korea, 135-080

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Samsung 10DR Implant™ System
Common Name:	Image Processing System
Device Classification:	System, Image Processing, 892.2050 90LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

Manufacturer:	Materialise N.V.
Device:	Materialise CT Modeller System
510(k) Number:	K970617
Date Received:	02/18/1997
Decision Date:	04/21/1997
Decision:	Substantially Equivalent
Panel Code device reviewed by: Radiology	
Panel Code device classified by: Radiology	
Product Code:	90LLZ
Classification:	Class II

Device Description: 21 CFR 807 92(a)(4)
The 10DR Implant™ is software developed for use in virtual surgery of a dental implant into the maxilla or a mandible, by examining the bone density of the implanting area and indicating whether the implant collides with the canal. The functions of 10DR Implant are as follows.

- 3D bone modeling
- Visualize the bone density of the embedded implant area in a maxilla (figure 1) or a mandible (figure 2).
- Detect and visualize a canal in the mandible.
- View the axial, cross-sectional, panoramic and panoramic projection images.

Indications for Use: 21 CFR 807 92(a)(5)
The Samsung 10 DR™ Implant system is intended for use as a software interface and image segmentation system for the transfer of imaging information from CT medical scanners to create a data file that can be used for a CAD or Rapid Prototyping System in dental implant simulation. Typical users of this system are trained professionals, including but not limited to physicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the Samsung 10DR Implant™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

1. The 10DR Implant system has been developed and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
2. The submission contains the results of a hazard analysis. All potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Samsung SDS Co., LTD
c/o Carl Alletto
Otech Inc.
1100 Lakeview Blvd.
Denton, Texas 76208

Re: K002062
Samsung 10DR Implant Software
Dated: August 14, 2000
Received: August 16, 2000
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Mr. Alletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

(Indications for Use Form)

510(k) Number: ___

Device Name:

10 DR™ Implant, Samsung SDS Co. Ltd.

Indications for Use:

The Samsung 10 DR™ Implant system is intended for use as a software interface and image segmentation system for the transfer of imaging information from CT medical scanners to create a data file that can be used for a CAD or Rapid Prototyping System in dental implant simulation.

Typical users of this system are trained professionals, including but not limited to physicians.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___V___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)

David A. Segal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002062